

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1899  
Telephone: 612-334-4100

**PURGED**

cc: HFI-35/FOI Staff  
DWA

November 15, 1996

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 97-11

Peggy L. Coyne  
President  
Presidents Specialty Healthcare  
715 Mt. View-Baken Park  
Rapid City, South Dakota 57702

Dear Mrs. Coyne:

During our October 29, 1996, inspection of your medical gas manufacturing facility located in Rapid City, SD, our investigator documented deviations from the Current Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations, Parts 210 and 211 (GMPR). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Deviations from GMPR include:

- Failure to establish written procedures for transfilling operations.
- Failure to document the daily calibration of the oxygen analyzer.
- Failure to document testing of filled oxygen cylinders.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may

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Peggy L. Coyne  
November 15, 1996

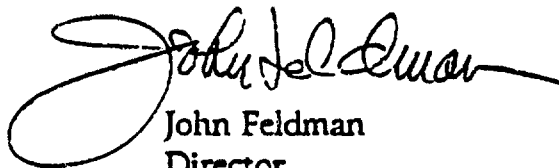
take this information into account when considering the award of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Minneapolis District Office, 240 Hennepin Avenue, Minneapolis, Minnesota 55401, Attention: Lawrence R. Murphy, Compliance Officer.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Feldman". The signature is fluid and cursive, with a large loop at the beginning.

John Feldman  
Director  
Minneapolis District

LRM/ccd